Original Article

Caudal tramadol bupivacaine combination for postoperative pain releif in subumbilical paediatric surgery

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Abstract

Background Regional anaesthesia in children provides the advantage of reduced requirements of other anaesthetic agents and of excellent analgesia introduction. Rational use of adjuvant with local anaesthetic in caudal route for prolonged optimal analgesia in paediatric population.

Objectives To evaluate the quality and duration of postoperative analgesia in children undergoing subumbilical surgeries with caudally administered mixture of tramadol and bupivacaine.

Methods Sixty children of ASA physical status I & II scheduled for elective subumbilical surgery were included in this prospective case-control study. Children were randomly assigned to receive caudal analgesia with plain bupivacaine (Group-I) and a mixture of tramadol-bupivacaine (Group-II) respectively. Blood pressure, heart rate, oxygen saturation and duration of analgesia were recorded postoperatively.

Results Study revealed that mean duration of caudal analgesia in Group-I and Group-II were 245.67 ± 6.94 and 612.05 ± 16.49 minutes respectively which was significantly longer (P<0.001) in Group-II. Mean number of postoperative analgesics were 2.97±0.50 and 1.78±0.50 in Group-I and Group-II which was statistically highly significant (P=0.000). Postoperative nausea and vomiting was significantly high in Group-II (P=0.019).

Conclusion Combination of tramadol with bupivacaine results in prolonged analgesia when administered in caudal route. In addition, tramadol is more useful in young children considering less respiratory depression than other opioids.

Key Words: Caudal tramadol-bupivacaine mixture, paediatric post operative analgesia.

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Introduction

Post-operative analgesia is essential to provide subjective comfort to restore the function of different organs and to allow the patient to breath, cough and move more easily. Regional anaesthetic techniques in paediatric patients have gained considerable popularity. The primary advantages of regional supplementation are lowering of general anaesthetic requirements and to provide intense post-operative analgesia[1].

Caudal anaesthesia is one of the most frequently used regional techniques in children, accounting for almost 50% of all regional techniques[2]. Many anaesthetic agents have been used for caudal analgesia in paediatric patients most common being

the lignocaine and bupivacaine. Although administration of bupivacaine into the caudal extradural space has been a standard method of providing post-operative analgesia for paediatric surgery, a single injection may have only a relatively short duration of action[3]. Attempts to overcome this problem by combining the local anaesthetic agents with other drugs such as adrenaline, clonidine[4], ketamine, or opioids[5] have met with varied degrees of success.

Tramadol hydrochloride is a synthetic opioid of the aminocyclohexanol group. Its dual mode of action (opioid and non-opioid) may provide some advantages over pure opioid analgesics. Specially considering the side effects[6]. Tramadol is not chemically related to opioids, but still it acts on opioid receptors. It is a racemic mixture of the two cis-isomers. The R(+)-isomer has some activity at the μ receptor, also inhibits serotonin (S-HT) uptake and S(-)-isomer inhibits noradrenaline uptake. Tramadol inhibits noradrenaline uptake and stimulates serotonin release and these are transmitted in the descending pathways which play an important role in its analgesic profile[7]. Caudal block with bupivacaine alone can provide analgesia for only three to four hours[8].

The aim of this study was to determine whether caudal administration of tramadol 2mg.kg^{-1} with bupivacaine prolongs the duration of analgesia compared with bupivacaine alone with respect to side effects and provides satisfactory analgesia in subumbilical paediatric surgery.

Methods

After approval of ethical committee, sixty children aged 2-10 years of ASA physical status I & II were selected randomly for this prospective case control study. Maintaining the inclusion and exclusion criteria, informed written consent were obtained from legal guardians after explaining them the purpose of this study.

Without pre-medication securing venous access general anaesthesia was induced with thiopentone (3-5 mg.kg^{-1}) after adequate pre-oxygenation. Tracheal intubations were facilitated with succinylcholine (1.5mg.kg^{-1}) and anaesthesia was maintained using nitrous oxide 66%, Halothane 0.5-1% in oxygen. Neuromuscular block were maintained with atracurium.

Children were allocated randomly into two groups (30 patients) and caudal analgesia was performed just after intubation and before starting surgery using a 23 gauge hypodermic needle under aseptic condition with the child in left lateral position. Group – I (Control group): children received 0.8ml.kg^{-1} of 0.25% plain bupivacaine plus 1ml normal saline. Group – II (Case group): children received 0.8ml.kg^{-1}) of 0.25% plain bupivacaine together with 2mg.kg^{-1} of tramadol in 1ml normal saline.

Child was placed in supine position and no analgesic supplement was given during operation. Surgery was started 15 minutes after caudal injection. Heart rate and oxygen saturation (SPO_2) were monitored continuously and arterial blood pressure was monitored every 5 minutes by electronic oscillometer. Residual neuromuscular block was antagonized with a mixture of neostigmin 50μg.kg^{-1} and atropine 20μg.kg^{-1} at the end of operation and duration of surgery was noted. The child was extubated in lateral recovery position. In post surgical ward the following parameters were recorded at 30 minutes interval for the first hour and at 2, 4, 6, 8, 12, and 24 hours after recovery from anaesthesia : heart rate, non invasive measurement of arterial blood pressure respiratory rate (RR) and oxygen saturation (S_pO_2) with pulse oximetry.

Pain score was assessed using modified TPPPS (toddler preschooler postoperative pain scale) to give a maximum score of 10 (Table-V) according to Tarbell et al[9]. Pain score more than 3 required administration of rescue analgesia either with diclofen sodium suppository (1mg.kg^{-1}) or oral paracetamol (20mg.kg^{-1}).

Total numbers of analgesic requirement in 24 hours postoperative period were recorded. Mean number of analgesic required in twenty four hours postoperatively were 2.97±0.50 and 1.78±0.50 in Group – I & II respectively (Fig 1).

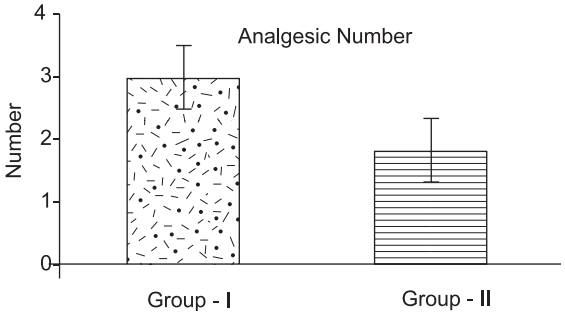

Fig 1 *Number of analgesic requirements*

The incidence of side effects if any occurred was recorded.

Data was collected on pre-designed data collection sheet and was analyzed for statistical significances by unpaired student's 't' test or chi-square (x^2) test as appropriate. P<0.05 was considered significant.

Results

There were no significant differences among the groups regarding demographic data and duration of surgery (Table I).

Haemodynamic data were analyzed by comparing heart rate (HR), systolic blood pressure (SBP). diastolic blood pressure (DBP) between two groups and no significant differences were observed as shown in Table II.

Mean durations of first analgesic requirement in the postoperative period were 245. 67 6.94 minutes in group – I and 612.05 16.49 minutes in group – II. There was statistically highly significant difference between two groups (P = 0.00) as shown in Table IV & Figure II.

The two groups were statistically matched for ventilator frequency (RR) and oxygen saturation (SpO_2) having no differences between them as shown in (Table III).

Table I *Patient characteristics and duration of surgery.*

Variables	Gr - I	Gr - II	't' value	P - value
Age (yrs)	5.30 ± 0.51	4.73 ± 0.46	0.83	0.408
Weight (kg)	14.43 ± 0.85	15.70 ± 0.85	1.06	0.295
Duration of surgery (min)	55.64 ± 2.46	64.33 ± 5.77	1.39	0.171

Values are expressed as mean±SD. Data are analyzed by Student's 't' test. p<0.05 significant

Table II *Changes of haemodynamic parameter*

Variables	Gr – I	Gr – II	't' value	P - value
HR/min	104.83 ± 1.87	108.20 ± 2.13	1.19	0.239
SBP (mm of Hg)	91.23 ± 1.50	86.67 ± 0.65	0.28	0.783
DBP (mm of Hg)	52.00 ± 1.65	47.67 ± 0.82	1.40	0.167

Values are expressed as mean±SD. Data are analyzed by Student's 't' test. p<0.05 significant

Table III *Changes of respiratory rate & Spo_2*

Variables	Gr – I	Gr – II	't' value	P – value
Respiratory rate	18.73 ± 0.64	20.40±0.75	1.70	0.095
SpO_2%	100.00±0.69	99.43±0.09	1.05	0.296

Mean -± SEM; P<0.05 – Significant.

Table IV *First analgesic requirements in minutes.*

Variable	Gr – I	Gr – II	P – value
1st dose analgesic rescue in minutes	245.67±6.94	612.05±16.49	0.00^{NS}

Mean - SEM; P<0.05 – Significant; P<0.01 highly significant. HS – highly significant.

Table V *Modified TPPPS pain score*

Variable	Score 0	Score 1	Score 2
Verbal complaint, cry	None	Once Only	> once
Groan / moan / grunt	None	Once only	> once
Facial expression	Neutral	Once grimace	Grimace > once
Restless motor behabiour	None	Once episode only	> once episode
Rub / touch painful area	None	Once only	> once

Mean number of analgesic required in 24 hours postoperatively were 2.97±0.50 in group-I and 1.78±0.50 in group-II which revealed statistically highly significant differences in analgesic requirement between two groups (P=0.00).

Though sedation score did not differ significantly between the two groups (P>0.05) but incidence of nausea/vomiting was significantly higher in group-II (P=0.019). It was mild and occurred once and well managed with safe anti emetic drugs like 5-HT_3 receptor antagonist e.g. Ondansetron ($0.1mg.kg^{-1}$) I/V or orally. No other side effects were seen.

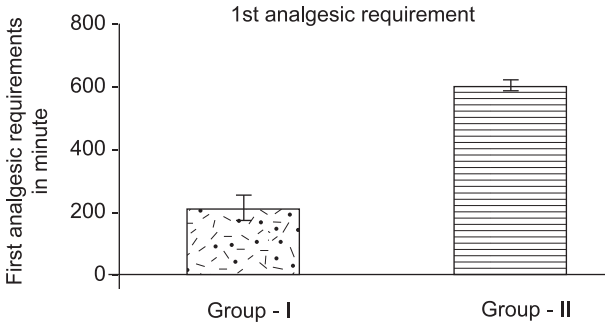

Fig 2 *First analgesic requirements in minute*

Discussion

Regional anaesthesia in children provides the advantage of reduced requirements for other anaesthetic agents and of excellent analgesia. The caudal approach to the epidural space has experienced a resurgence of interest among paediatric anaesthesiologists[10]. Any surgical procedure below umbilicus can be performed under caudal anaesthesia and can be benefited from the post operative analgesia that the caudal block might provide[11].

Caudal administration of bupivacaine is a wide-spread regional anaesthetic technique for intra and post-operative analgesia during various surgical procedures in children. The addition of opioid to bupivacaine is known to prolong the duration of caudal analgesia but the possibility of adverse effects like respiratory depression, pruritus etc. has limited the use of such mixture[12]. Caudal administration of bupivacaine has duration of action of only 2-4 hours[4]. As a result, systemic analgesia is usually required as the block wears off. It was observed that the peak serum concentration of tramadol occurred at 0.55 ± 0.11 hours after caudal administration[13] while Lintz et al[14] observed that serum concentration after i.m. injection of tramadol in healthy adults occurred at 0.75±0.38 hours.

In this study, addition of tramadol 2mg/kg to bupivacaine administered caudally provided post-operative analgesia for 612.05±16.49 minutes in comparison to 245.67±6.94 minutes with caudally administered bupivacaine alone. This results is in agreement with the results obtained by Stephan et al. who showed that tramadol when added to mepivacaine significantly prolong the duration of a brachial plexus block[15]. In our study all children (100%) in both groups required rescue analgesic.

On the basis of mean number of analgesic required in 24 hours post-operative period (POP), significantly less supplemental diclofenac sodium suppository was required in bupivacaine - tramadol group (1.78±0.50) compared to bupivacaine group (2.97±0.50). Modified TPPPS (Toddler Pre Schooler Post-operative Pain Scale) score[9] of more than 3 out of 10 (rather than 7 as in the original) was the indication of first rescue analgesic in all children. There was no significant difference in two groups as regards to haemodynamic parameters (heart rate, arterial blood pressure). In this study, incidence of nausea and vomiting was observed in bupivacaine - tramadol (group II) mixture group (16.7%)

probably due to its systemic absorption, which was mild and well managed with antiemetic drugs. No other adverse effects like facial and body flushing, urinary retention, pruritus, hypotension and any signs of motor weakness were observed in this study. So a combination of bupivacaine – tramadol mixture in caudal route significantly increases the potency and duration of caudal analgesia with minimal adverse effects than the bupivacaine or tramadol alone.Our results concluded that, addition of tramadol to bupivacaine in caudal route provides an optimal analgesia for a longer period than bupivacaine alone. Moreover as an adjunct to bupivacaine, tramadol might be more useful in young children considering less respiratory depression than the other opioids.

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